(2)

Supreme Court, U.S.
FILED
AUG 11 2000
OFFICE OF THE CLERK

No. 00-71

IN THE

Supreme Court of the United States

MEAD JOHNSON & CO.,

Petitioner,

v.

ABBOTT LABORATORIES,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

BRIEF IN OPPOSITION

DAVID O. TITTLE
BINGHAM SUMMERS
WELSH & SPILMAN
2700 Market Tower
10 West Market Street
Indianapolis, IN 46204-2982
(317) 635-8900

THOMAS C. MORRISON
Counsel of Record
ERIK HAAS
PATTERSON, BELKNAP,
WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036-6710
(212) 336-2000

Of Counsel:

LAURA J. SCHUMACHER
ABBOTT LABORATORIES

Attorneys for Respondent

161534

Counsel Press LLC
(800) 274-3321 • (800) 359-6859

COUNTER-STATEMENT OF QUESTION PRESENTED

Was the Seventh Circuit correct that, where an advertising claim is based on test data, it is inappropriate for a court to rely on the views of consumers to determine the adequacy and sufficiency of the supporting data?

STATEMENT PURSUANT TO RULE 29.6

Respondent, Abbott Laboratories, has no parent corporation and no publicly held company owns 10% or more of its stock.

TABLE OF CONTENTS

	Page
Counter-Statement of Question Presented	i
Statement Pursuant to Rule 29.6	ii
Table of Contents	iii
Table of Cited Authorities	vi
Table of Appendices	xi
Counter-Statement of the Case	1
A. Abbott's "1st Choice of Doctors" Claim	3
B. The Twelve Doctor Surveys	3
1. Surveys Where A Majority Of Doctors Preferred SIMILAC	4
C. Mead's Consumer Research	8
The Decision Below	10
Reasons for Denying the Writ	12
I. Prior To The District Court's Decision, No Court Had Ever Relied On Consumer Research To Determine The Adequacy Of An Advertiser's Claim Substantiation	12

Contents

		Page
1.	Proof of Efficacy	14
2.	Meaningful Superiority	14
3.	Statistical Significance	14
4.	Duration/Speed of Action	14
5.	The Proper Universe	15
6.	Tallying the Data	15
7.	Level of Statistical Significance	15
8.	Accounting For "No Preference" Votes	15
9.	Doctor Recommendation Surveys	16
II.	The Seventh Circuit's Decision Is Consistent With The Decisions Of Other Circuits Regarding The Role Of Consumer Research	17
1.	Literally False Claims	19
2.	Misleading Claims	20
3.	Literally Truthful Claims	20
4.	Non-Misleading Claims	21

Contents

Page

III. The Seventh Circuit's Decision Is Consistent With FTC Advertising Standards 21

Conclusion 24

TABLE OF CITED AUTHORITIES

Page

Cases:

Abbott Laboratories v. Gerber Products Co., 979 F. Supp. 569 (W.D. Mich. 1997) 15

Abbott Laboratories v. Mead Johnson & Co., 971 F.2d 6 (7th Cir. 1992) 14, 19

ALPO Petfoods, Inc. v. Ralston Purina Co., 720 F. Supp. 194 (D.D.C. 1989), *aff'd in part and rev'd and vacated in part on other grounds*, 913 F.2d 958 (D.C. Cir. 1990) 14, 16

American Council of Certified Podiatric Physicians & Surgeons v. American Bd. of Podiatric Surgery, 185 F.3d 606 (6th Cir. 1999) 19

American Home Products Corp. v. Johnson & Johnson, 577 F.2d 160 (2d Cir. 1978) 14, 18

American Home Products Corp. v. Johnson & Johnson, 654 F. Supp. 568 (S.D.N.Y. 1987) ... 15, 16

Avis Rent A Car Systems v. The Hertz Corp., 782 F.2d 381 (2d Cir. 1986) 20

Avon Products Inc. v. S.C. Johnson & Son, Inc., 1994 WL 267836 (S.D.N.Y. 1994) 15

BASF Corp. v. Old World Trading Co., 41 F.3d 1081 (7th Cir. 1994) 13

Cited Authorities

Page

BellSouth Adver. & Publ'g Corp. v. Lambert Publ'g, 45 F. Supp. 2d 1316 (S.D. Ala. 1999), *aff'd without op.*, 207 F.3d 663 (11th Cir. 2000) 21

Better Business Bureau of Houston v. Medical Directors, Inc., 681 F.2d 397 (5th Cir. 1982) ... 20

Castrol, Inc. v. Pennzoil Co., 987 F.2d 939 (3d Cir. 1993) 14, 19

Castrol, Inc. v. Quaker State Corp., 977 F.2d 57 (2d Cir. 1992) 14

Church & Dwight Co. v. S.C. Johnson & Son, Inc., 873 F. Supp. 893 (D.N.J. 1994) 15

Ciba-Geigy Corp. v. Thompson Medical Co., 672 F. Supp. 679 (S.D.N.Y. 1985 and 1984) 14

Coca-Cola Co. v. Tropicana Products, Inc., 690 F.2d 312 (2d Cir. 1982) 20

Cottrell, Ltd. v. Biotrol Int'l, Inc., 191 F.3d 1248 (10th Cir. 1999) 20

Gillette Co. v. Norelco Consumer Products Co., 946 F. Supp. 115 (D. Mass. 1996) 15

Glaxo Warner-Lambert OTC G.P. v. Johnson & Johnson Merck Consumer Pharmaceuticals Co., 935 F. Supp. 327 (S.D.N.Y. 1996) 20

Cited Authorities

Page

In re American Home Prods. Corp., 98 F.T.C. 136 (1981), *aff'd*, 695 F.2d 681 (3d Cir. 1982) 22

In re Bristol-Myers Co., 102 F.T.C. 21 (1983), *aff'd*, 738 F.2d 554 (2d Cir. 1984) 22

In re Del Pharms., Inc., No. 972-3084 (F.T.C. 1998) 22

In re Gerber Prods. Co., 62 Fed. Reg. 13619 (1997) 22, 23

In re Pfizer, 81 F.T.C. 23 (1972) 21

In re Standard Brands, Inc., 97 F.T.C. 233 (1981) 22

Johnson & Johnson v. GAC Int'l, Inc., 862 F.2d 975 (2d Cir. 1988) 20

Johnson & Johnson-Merck Consumer Pharms. Co. v. Rhone-Poulenc Rorer Pharms., 19 F.3d 125 (3d Cir. 1994) 21

Johnson & Johnson-Merck Consumer Pharmaceuticals Co. v. Smithkline Beecham Corp., 960 F.2d 294 (2d Cir. 1992) 17, 18, 21

L&F Prods. v. Procter & Gamble Co., 45 F.3d 709 (2d Cir. 1995) 20, 21

Cited Authorities

Page

McNeil-P.P.C., Inc. v. Bristol-Myers Squibb Co., 938 F.2d 1544 (2d Cir. 1991) 13, 14, 19

McNeilab, Inc. v. American Home Products Corp., 675 F. Supp. 819 (S.D.N.Y. 1987), *aff'd*, 848 F.2d 34 (2d Cir. 1988) 15

Philip Morris, Inc. v. Loew's Theatres, Inc., 511 F. Supp. 855 (S.D.N.Y. 1980) 15

Porous Media Corp. v. Pall Corp., 110 F.3d 1329 (8th Cir. 1997) 20

Porter & Dietsch, Inc. v. Federal Trade Commission, 605 F.2d 294 (7th Cir. 1979) 21

PPX Enterprises, Inc. v. Audiofidelity Enterprises, Inc., 818 F.2d 266 (2d Cir. 1987) 20

Procter & Gamble Co. v. Chesebrough-Pond's, 747 F.2d 114 (2d Cir. 1984) 13

Rhone-Poulenc Rorer Pharmaceuticals, Inc. v. Marion Merrell-Dow, 93 F.3d 511 (8th Cir. 1996) 19

R.J. Reynolds Tobacco Co. v. Loew's Theatres, Inc., 511 F. Supp. 867 (S.D.N.Y. 1980) 15

Cited Authorities

Page

Smithkline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson Merck Consumer Pharmaceuticals, Co., 1996 WL 280810 (S.D.N.Y. 1996) 14

Southland Sod Farms v. Stover Seed Co., 108 F.3d 1134 (9th Cir. 1997) 13

United Indus. Corp. v. The Clorox Co., 140 F.3d 1175 (8th Cir. 1998) 20

Vidal Sassoon, Inc. v. Bristol-Myers Co., 661 F.2d 272 (2d Cir. 1981) 18

Warner-Lambert Co. v. BreathAsure, Inc., 204 F.3d 87 (3d Cir. 2000) 19

William H. Morris Co. v. Group W Inc., 66 F.3d 255 (9th Cir. 1995) 20

TABLE OF APPENDICES

	Page
Appendix A — Similac Product Label	1a
Appendix B — Professional Endorsement Claims Appearing In Recent National Advertising	2a
Appendix C — Response To Q-5 In Ivan Ross Survey	5a

COUNTER-STATEMENT OF THE CASE

This false advertising case involves a straightforward medical endorsement claim made by respondent Abbott Laboratories: that SIMILAC Infant Formula is the "1st Choice of Doctors". The claim is similar to those made for dozens of well-known health care products. Medical endorsement claims are "objectively verifiable": they can — and indeed must — be substantiated by surveys of doctors or other medical professionals. Whether a particular survey substantiates the claim in question depends upon the methodological validity of the survey and a statistical analysis of its results. In this case, twelve doctor surveys — eight of them commissioned by petitioner Mead Johnson ("Mead") — unanimously show that SIMILAC is significantly preferred by doctors over Mead's ENFAMIL.

At Mead's urging, the District Court dealt with Abbott's claim in an extraordinary manner. Under the pretense that it was utilizing consumer research to interpret the "message" of the claim, Mead proffered the results of a consumer survey conducted by its consultant, Dr. Ivan Ross. By inviting the respondents to guess as to the *level* of doctor preference for SIMILAC in order for the claim to be true, Dr. Ross elicited consumer opinion that a *majority* of doctors surveyed must prefer SIMILAC. The District Court accepted this survey as proof that Abbott's claim somehow communicates the message that at least 50% of doctors recommend SIMILAC over ENFAMIL.

The District Court's ruling was an unprecedented one. Had it stood, it would have had enormous consequences for companies that utilize professional endorsement claims, or other objectively verifiable claims, in their advertising. Prior to this

case, questions regarding the adequacy of an advertiser's claim substantiation have been the province of scientists, statisticians and market research experts. But under the District Court's decision, the adequacy of the advertiser's substantiation was suddenly turned into a consumer plebiscite. The District Court's rationale would have been applicable to the evaluation of substantiation for all types of objectively verifiable claims, not just medical endorsement claims. Under the District Court's approach, advertisers would never know whether the substantiation they possessed was adequate to support their advertising; the sufficiency of that substantiation would always be subject to the whims of a consumer survey commissioned by a resourceful competitor.

The Seventh Circuit rightly rejected the District Court's novel approach. While acknowledging that consumer research is properly used in false advertising cases to determine the *meaning* of vague or ambiguous advertising claims, the court ruled that consumer research may not be used to determine the *level of substantiation*, or verification, that an advertiser should possess in order to render its advertising truthful.

Contrary to Mead's argument (Pet. 1), the Seventh Circuit's decision does not threaten to "turn 20 years of Lanham Act jurisprudence on its head." To the contrary, it was the District Court's decision that turned advertising law upside down. The Seventh Circuit wisely returned matters of claim substantiation to the playing field where they belong, i.e., the testimony of scientists, statisticians and market research experts. The Seventh Circuit's decision is consistent with well-established Lanham Act jurisprudence and should not be disturbed.

A. Abbott's "1st Choice of Doctors" Claim

Abbott's claim, in its entirety, is that SIMILAC is the:

"1st Choice of Doctors."

This is Abbott's primary claim for SIMILAC. It appears by itself inside a blue ribbon on the label of each of the 64 different packages in which SIMILAC is sold. While it also appears in hundreds of educational and promotional materials targeted to consumers, it generally appears as a free-standing claim that is unamplified by other advertising copy. At no time has Abbott ever stated, suggested or implied that a particular number or percentage of doctors choose SIMILAC over other brands. A typical SIMILAC label showing this unadorned claim is annexed as Appendix A.

Abbott's claim is a typical professional endorsement claim. It communicates the obvious message that doctors recommend SIMILAC more than any other brand. Such claims are common for medical products sold to consumers. As can be seen from the list of claims presented in Appendix B, many leading health care products are promoted as the brand most often recommended by doctors. Like Abbott's claim, none of these claims refers to the number or percentage of doctors who share the preference for the product in question.

B. The Twelve Doctor Surveys

To substantiate its "1st Choice of Doctors" claim, Abbott commissioned a series of doctor surveys by independent market research firms. As it turned out, Mead had also commissioned several doctor surveys in the normal course of its business. In addition, both parties were privy to doctor surveys conducted

by third parties, such as pediatric magazines; these surveys included questions relating to doctors' infant formula preferences.

All told, twelve doctor surveys were before the trial court. In all twelve, SIMILAC was significantly preferred over ENFAMIL. In most cases, the preference was by a ratio of approximately 2 to 1 (MJ App. C at 10a).[1] The Seventh Circuit recognized that a 2 to 1 preference could be meaningless if the "absolute" preference levels were extremely low, such as 1% or 2% (*Id.*). But that was not the case here. Set forth below are the results from the twelve surveys.

1. Surveys Where A Majority Of Doctors Preferred SIMILAC

(1) Glickman Study (MJ App. D at 56a)

Question: "Which of the following routine infant formulas, if any, is your 'first choice' for a MILK-based feeding?"

SIMILAC	52%
ENFAMIL	34%

(2) Burke Survey (*Id.* at 64a)

Question: "Which of the following infant formulas, if any, is your 'first choice' for a MILK-based feeding?"

SIMILAC	55.5%
ENFAMIL	37.2%

1. References to "MJ App." refer to the appendices to Mead's Petition.

(3) Mead's Tracking Study (*Id.* at 74a)

Question: "What one brand of infant formula do you recommend most often?"

SIMILAC	63%
ENFAMIL	32%

(4) Mead's 3-City Tracking Study (*Id.* at 75a)

Question: "What one brand of infant formula do you recommend most often?"

SIMILAC	64%
ENFAMIL	31%

(5) Wirthlin Worldwide (*Id.* at 77a-78a)

Question: "If you had to choose, which brand of infant formula do you personally prefer?"

SIMILAC	52%
ENFAMIL	23%

(6) Contemporary Pediatrics (*Id.* at 70a)

Question: "For each product category you recommend OTC products, which BRAND NAME PRODUCTS do you recommend most often?

SIMILAC	55.6%
ENFAMIL	39.1%

(7) Market Measures (*Id.* at 79a)

Question: "When you do make a specific recommendation of a single non-specialized (routine) milk-based formula, which brand do you recommend as your Infant Formula of Choice?"

SIMILAC	60%
ENFAMIL	23%[2]

2. Surveys Where A Plurality Of Doctors Preferred SIMILAC

(1) Cooper Research Tracking Study (*Id.* at 67a)

Question: "Do you have a single preferred brand of infant formula that you usually recommend to your patients?"

SIMILAC	36%
ENFAMIL	16%

(2) Mead Tracking Study (*Id.* at 73a)

Question: "What ONE brand of infant formula do you recommend most often?"

SIMILAC	44%
ENFAMIL	40%

---

2. The District Court removed studies six and seven from the "majority" preference category by accepting retabulations, made by Mead's attorneys, that reduced the preference for SIMILAC below 50%.

(3) Ivan Ross Litigation Study (*Id.* at 52a)

Question: "First, thinking only about two brands of nonspecialized milk-based infant formula with iron, SIMILAC With Iron and ENFAMIL With Iron, do you or don't you have a preference between the two brands?" (If 'yes'): Which brand do you prefer?"

SIMILAC	25%
ENFAMIL	10%

(4) Medprobe Study (*Id.* at 75a)

Question: "Of the following choices, which is most accurate for you personally? You primarily recommend. . . ."

SIMILAC	44%
ENFAMIL	17%

(5) Market Measures, Inc. (*Id.* at 76a)

Question: "When you do make a specific recommendation of a single non-specialized (routine) milk-based formula, which brand do you recommend as your Infant Formula of Choice?"

SIMILAC	34%
ENFAMIL	25%

This data vividly demonstrates the validity of the "1st Choice" claim. It also demonstrates the fallacy of the approach adopted by the District Court. Under that approach, rather than focusing on whether this data is valid and meaningful in the eyes of market research experts, the focus was on the level of data consumers believe should be necessary, even though they have no knowledge or experience in evaluating market research. This approach, had it been permitted to stand, would have been a disservice to the advertising and marketing research communities by saddling them with perpetual uncertainty as to the level of substantiation that is required for professional endorsement claims. The Seventh Circuit properly recognized that the sufficiency of an advertiser's substantiation must be measured against uniform principles that the advertiser can discern in advance, rather than against after-the-fact data generated by a competitor's survey.

C. Mead's Consumer Research

The District Court's conclusion that Abbott's claim communicates the message that a *majority* of doctors choose SIMILAC over ENFAMIL was based upon a consumer survey commissioned by Mead's attorneys and conducted by Professor Ivan Ross. The first few questions were standard questions that asked about the message communicated by Abbott's claim (MJ App. D at 38a-39a). Those questions yielded no playback regarding the percentage of doctors that choose or recommend SIMILAC. This is undoubtedly why Dr. Ross included Question 5. Question 5, however, did not ask consumers to interpret the claim. Rather, it asked them to opine about the percentage of doctors who would have to prefer SIMILAC *in order for the claim to be true*. Thus it asked (*Id.* at 39a-40a):

> Now, suppose that a *survey* of doctors had been conducted by the company which makes this product and that they were relying on the *results* of that survey to make the statement you see *here*. ["1st Choice of Doctors"]. If you have an opinion, in order for this statement to be *true*, *what percent* of those doctors would have had to say *this* product was their *first choice*?

This question elicited a wide range of opinion. While 52% of the respondents believed that at least 50% should be required, 24% believed that 90% was required and 7% believed that 100% was required. (A breakdown of these responses is shown in Abbott's Appendix C.) The District Court utilized these responses to impose a requirement that at least 50% of doctors must choose SIMILAC in order for the claim to be true. Yet there was no magic about the 50% level: 60% of the respondents said the requirement should be 75% or higher, 46% said it should be 80% or higher, and 33% said it should be 90% or higher (*see* Appendix C). Under Mead's theory, the District Court could just as easily have imposed any of these higher levels as the requisite level of preference. Likewise, if an identical claim were made for a different product (*e.g.*, VICKS CHLORASEPTIC is "#1 Dr. Recommended"), another court in another lawsuit would be free to impose any of these higher levels as the requisite percentage. This would create permanent uncertainty as to what level of preference must be shown in order to substantiate a professional endorsement claim. The Seventh Circuit therefore ruled that the District Court's reliance on this question, and the follow-up Question 6 (which provided a hypothetical set of data and asked whether the claim would be truthful in light of that data), was erroneous.

THE DECISION BELOW

Mead has mischaracterized the decision below. According to Mead, the Seventh Circuit has created a "gargantuan hurdle" for Lanham Act plaintiffs by "categorically rejecting as irrelevant" the perceptions of consumers to whom advertising claims are targeted (Pet. 5). According to Mead, this represents a sea change in Lanham Act advertising jurisprudence because (Pet. 3):

> Survey evidence as to consumer understanding of the message conveyed . . . has been critical in such litigation.

But Mead's argument is based on a mistaken premise. Its premise is that the consumer research that the District Court relied on was evidence of consumer understanding of "the message conveyed" by Abbott's claim. But the research was not addressed to consumer perception of the *message* conveyed by the "1st Choice" claim; rather, it was addressed to consumer opinion regarding the *level of substantiation* Abbott possessed to support its claim.

The Seventh Circuit made this destination clear in both of its opinions. In its original opinion, the Seventh Circuit pointed out that it was improper for the District Court to utilize Mead's survey to determine the *level* of substantiation that Abbott must possess in order to substantiate this "objectively verifiable" claim (MJ App. C at 14a):

> There is a deeper problem: the use of a survey in the first place. Surveys are accepted ways to probe for things such as confusion about the source of goods, for confusion depends on the effect of a

> phrase or trade dress on the consumer. . . . So far as we can tell, however, never before has survey research been used to determine the meaning of words, or to set the standard to which objectively verifiable claims must be held.

Thereafter, Mead filed a Petition for Rehearing *En Banc*. In that petition, Mead made the same argument that it makes here: that the decision is at odds with established case law that encourages the use of survey evidence to determine the message communicated by advertising that is vague or ambiguous. The Seventh Circuit rejected this interpretation of its decision. As it explained (MJ App. A at 5a-6a):

> None of this calls into question the understanding, expressed by many decisions, that whether a claim is either "false" or "misleading" is an issue of fact rather than law. See *Abbott Laboratories v. Mead Johnson & Co.*, 971 F.2d at 13-15; *Castrol, Inc. v. Pennzoil Co.*, 987 F.2d 939, 943-45 (3d Cir. 1993); *Johnson & Johnson * Merck Consumer Pharmaceuticals Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 298 (2d Cir. 1992). Our fundamental conclusion is that a producer cannot make a factual issue just by conducting surveys about how science is done (or, worse, about how surveys should be conducted). The sort of survey evidence Mead Johnson gathered would not support a conclusion by a reasonable person that Abbott's claim either was false or implied a falsehood.

Accordingly, Mead's entire Petition, including its "Question Presented", proceeds from an erroneous premise.

Just as Mead's survey does not represent evidence of consumer "take-away" of the message communicated by Abbott's claim, the Seventh Circuit's opinion does not represent a repudiation of the proper role of consumer surveys in Lanham Act cases. The error in this case was Mead's: it commissioned consumer research that went far beyond the permissible inquiry into advertising communication and, instead, probed consumer views about the nature and quality of the advertiser's substantiation. The Seventh Circuit properly rejected this unprecedented use of consumer research.

REASONS FOR DENYING THE WRIT

There is nothing aberrational about the Seventh Circuit's decision. It is consistent with Lanham Act case law regarding claim substantiation and consumer surveys and it is consistent with advertising standards followed by the Federal Trade Commission.

I.

PRIOR TO THE DISTRICT COURT'S DECISION, NO COURT HAD EVER RELIED ON CONSUMER RESEARCH TO DETERMINE THE ADEQUACY OF AN ADVERTISER'S CLAIM SUBSTANTIATION

Abbott agrees with Mead that the "1st Choice of Doctors" claim is an "establishment claim." An "establishment claim" is a claim that represents that an objectively verifiable product attribute has been proven by medical, scientific or other evidence. In such cases, the truth or falsity of the claim is measured by whether the supporting evidence possessed by the advertiser is sufficient to

"establish" the claim in question. *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997); *BASF Corp. v. Old World Trading Co.*, 41 F.3d 1081, 1089 (7th Cir. 1994); *McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d 1544, 1549 (2d Cir. 1991).

In the leading case on establishment claims, *Procter & Gamble Co. v. Chesebrough-Pond's*, 747 F.2d 114, 119 (2d Cir. 1984), the Second Circuit held that, in judging the adequacy of the data offered as substantiation, the court must consider "all relevant circumstances" including:

(i) the state of the testing art;

(ii) the existence and feasibility of superior procedures;

(iii) the objectivity and skill of the persons conducting the tests;

(iv) the accuracy of their reports; and

(v) the results of other pertinent tests.

This inquiry does not, however, extend to the views of *consumers* regarding the adequacy of the data. To the contrary, the court must determine the adequacy of the substantiation based upon the testimony of scientists, statisticians and other experts. As the *Procter & Gamble* court explained (747 F.2d at 120):

> That a district court, sitting as trier of the facts, must consider, analyze and weigh expert testimony regarding clinical testing standards, procedures and results, has long been recognized.

In accordance with this principle, issues relating to claim substantiation are routinely decided on the basis of expert testimony, not consumer surveys. Such issues include:

1. ***Proof of Efficacy***: The degree of scientific proof that is necessary to show that a product is efficacious.[3]

2. ***Meaningful Superiority***: Whether a point of differentiation between two products is sufficiently meaningful that it can provide the basis for a superiority claim.[4]

3. ***Statistical Significance***: Whether measurable product differences are statistically significant, and therefore capable of supporting a comparative claim.[5]

4. ***Duration/Speed of Action***: Whether a drug can be said to start to work faster, or last longer, than a competing drug.[6]

---

3. *ALPO Petfoods, Inc. v. Ralston Purina Co.*, 720 F. Supp. 194, 203-5 (D.D.C. 1989), *aff'd in part and rev'd and vacated in part on other grounds*, 913 F.2d 958 (D.C. Cir. 1990) (health claim for a dog food); *Ciba-Geigy Corp. v. Thompson Medical Co.*, 672 F. Supp. 679 and Appendix I (S.D.N.Y. 1985 and 1984) (efficacy levels for diet drugs).

4. *Castrol, Inc. v. Pennzoil Co.*, 987 F.2d 939 (3d Cir. 1993) and *Castrol, Inc. v. Quaker State Corp.*, 977 F.2d 57 (2d Cir. 1992) (whether differences in motor oil viscosity provide a meaningful performance advantage); *Abbott Laboratories v. Mead Johnson & Co.*, 971 F.2d 6 (7th Cir. 1992) (whether difference in osmolality levels provides a meaningful benefit to infants).

5. *McNeil-P.P.C., Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d 1544, 1546-48 (2d Cir. 1991); *American Home Products Corp. v. Johnson & Johnson*, 577 F.2d 160, 167-68 (2d Cir. 1978).

6. *Ciba-Geigy Corp. v. Thompson Medical Co., supra* (duration claims for diet drugs); *Smithkline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson Merck Consumer Pharmaceuticals, Co.*, 1996 WL 280810 at *12 (S.D.N.Y. 1996) (onset of action for antacids).

The same rule holds true for establishment claims that are based on objectively verifiable market research. In such cases, whether the market research is adequate to substantiate the claim in question is determined by industry standards and by the testimony of experts in marketing, market research and statistics. For example:

5. ***The Proper Universe*****:** Whether the survey in question covered the appropriate "universe" of respondents.[7]

6. ***Tallying the Data*****:** Whether the advertiser has presented the survey results in a way that misrepresents the underlying data.[8]

7. ***Level of Statistical Significance*****:** What level of statistical confidence must be achieved in order to render a preference for one of the products significant.[9]

8. ***Accounting For "No Preference" Votes*****:** How to account for those respondents who have no preference for any of the products in the study.[10]

---

7. *E.g.*, *Abbott Laboratories v. Gerber Products Co.*, 979 F. Supp. 569, 574 (W.D. Mich. 1997); *Church & Dwight Co. v. S.C. Johnson & Son, Inc.*, 873 F. Supp. 893, 907 (D.N.J. 1994); *McNeilab, Inc. v. American Home Products Corp.*, 675 F. Supp. 819, 823 (S.D.N.Y. 1987), *aff'd*, 848 F.2d 34 (2d Cir. 1988).

8. *Philip Morris, Inc. v. Loew's Theatres, Inc.*, 511 F. Supp. 855, 857 (S.D.N.Y. 1980); *R.J. Reynolds Tobacco Co. v. Loew's Theatres, Inc.*, 511 F. Supp. 867, 872 (S.D.N.Y. 1980).

9. *Gillette Co. v. Norelco Consumer Products Co.*, 946 F. Supp. 115, 125, n.7 (D. Mass. 1996); *Avon Products Inc. v. S.C. Johnson & Son, Inc.*, 1994 WL 267836 at *5 (S.D.N.Y. 1994); *Abbott v. Gerber*, *supra*, 979 F. Supp. at 575, n.6.

10. *American Home Products Corp. v. Johnson & Johnson*, 654 F. Supp. 568, 587-88 (S.D.N.Y. 1987).

9. *Doctor Recommendation Surveys*: In the two reported cases dealing specifically with doctor recommendation claims, the courts looked to the views of marketing and market research experts to determine whether the claims were adequately substantiated.[11]

Thus, while consumer research is relevant to determine the message conveyed by an ambiguous advertising claim, it is irrelevant to determine whether the claim is adequately substantiated. In this case, it was no more proper for Mead to ask consumers what percentage of doctors must prefer SIMILAC in order for the claim to be true than it would be to ask consumers such questions as:

- How many clinical studies an advertiser must have in order to demonstrate a drug's superiority over another brand; or

- What degree of statistical significance should be required in order to justify the use of comparative data; or

- Whether a consumer preference claim can be supported by a survey that includes consumers who do not use the products in question.

In other words, the question of what percentage of doctors must prefer the advertiser's product in order for a

---

11. *American Home Products Corp. v. Johnson & Johnson*, 654 F. Supp. 568, 587-88 (S.D.N.Y. 1987) ("70,000 doctors recommend ANACIN-3" upheld despite the fact that 70,000 doctors represented only 10% of all doctors in the country); *ALPO Petfoods, Inc. v. Ralston-Purina Co.*, 720 F. Supp. 194 (D.D.C. 1989) (ALPO preferred "2 to 1" over other leading brands found misleading based on flaws in the survey methodology).

doctor preference claim to be true is not an issue that may be put to a consumer vote. Yet that is precisely what the District Court allowed Mead to do. The Seventh Circuit wisely overruled this misuse of consumer research. As it stated in its initial opinion (MJ App. C at 14a):

> Never before has survey research been used to set the standard to which objectively verifiable claims must be held.

And as it added in its Opinion on reargument (MJ App. A at 5a):

> Our fundamental conclusion is that a producer cannot make a factual issue just by conducting surveys about how science is done (or, worse, about how surveys should be conducted).

This conclusion is correct and is in accordance with well-settled Lanham Act law.

II.

THE SEVENTH CIRCUIT'S DECISION IS CONSISTENT WITH THE DECISIONS OF OTHER CIRCUITS REGARDING THE ROLE OF CONSUMER RESEARCH

Consumer research can play an important role in false advertising litigation. Even though a statement is not literally false, in the context of the overall ad it may nevertheless convey a message that is misleading. In such cases, the implied message is frequently proven through the use of consumer research. *E.g.*, *Johnson & Johnson-Merck Consumer Pharmaceuticals Co. v. Smithkline Beecham*

Corp., 960 F.2d 294 (2d Cir. 1992); *Vidal Sassoon, Inc. v. Bristol-Myers Co.*, 661 F.2d 272 (2d Cir. 1981); *American Home Products Corp. v. Johnson & Johnson*, 577 F.2d 160, 169 (2d Cir. 1978). In this case, for example, the District Court properly considered Mead's consumer survey in connection with Mead's contention that the "1st Choice of Doctors" claim communicates an implied message that SIMILAC is the first choice of doctors *because it provides superior clinical benefits to infants*. Despite Mead's survey, the District Court rejected this interpretation (MJ App. D at 49a).

The Seventh Circuit fully recognized the role of consumer surveys in false advertising cases. In fact, it considered Mead's survey in connection with its determination of the meaning of Abbott's claim. Thus it pointed out that the "opening set of questions" (*i.e.*, the "open-ended" communication questions) were perfectly appropriate but showed that the "1st Choice" claim communicates little more than that SIMILAC is a high quality product. As the court stated (MJ App. C at 14a):

> If consumers took away from "1st Choice of Doctors" the implication that Similac is a high-quality product, as the author of the survey concluded, then they were not deceived (this Mead Johnson concedes); we doubt that it is proper to draw more from this survey.

On the motion for reargument, the Court rejected Mead's contention that its opinion ignored the role of surveys in false advertising cases. As noted above (*see* pp. 10-11, *supra*), the court explained that consumer surveys are not a proper way to determine whether the advertiser's substantiation for an objectively verifiable claim is sufficient (MJ App. A at 5a-6a).

In truth, it is Mead, not the Seventh Circuit, that is misapplying the law regarding consumer research. Not only is Mead attempting to use consumer research for an improper purpose (to evaluate the advertiser's substantiation), it is also espousing a point of view that would make consumer research sacrosanct and would force the courts to give uncritical acceptance to a plaintiff's consumer research. Such a rule would be unwise and unprecedented.

Like other circuits, the Seventh Circuit has long recognized that consumer surveys are a tool to assist the court in determining the message communicated by vague or ambiguous advertising statements. Because surveys are merely a tool, they can be accepted, rejected, or partially accepted and partially rejected; there is simply no requirement that a court must give controlling weight to a particular question in a survey. Accordingly, the courts routinely reach conclusions about advertisements that are unsupported by, or inconsistent with, consumer research. For example:

1. ***Literally False Claims***: The courts recognize that an ad may be found to be literally false without regard to consumer research.[12] In some cases, appellate courts have even found advertising to be literally false despite the trial

---

12. *Warner-Lambert Co. v. BreathAsure, Inc.*, 204 F.3d 87, 96 (3d Cir. 2000); *American Council of Certified Podiatric Physicians & Surgeons v. American Bd. of Podiatric Surgery*, 185 F.3d 606, 614 (6th Cir. 1999); *Rhone-Poulenc Rorer Pharmaceuticals, Inc. v. Marion Merrell-Dow*, 93 F.3d 511, 516 (8th Cir. 1996); *Castrol Inc. v. Pennzoil Co.*, 987 F.2d 939, 943 (3d Cir. 1993); *Abbott Laboratories v. Mead Johnson & Co.*, 971 F.2d 6, 14-15 (7th Cir. 1992); *McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d 1544, 1549 (2d Cir. 1991).

court's *rejection* of survey research that purportedly proved the advertising's falsity.[13]

2. *Misleading Claims*: While a consumer survey is the most persuasive way to prove that a literally truthful claim conveys an overall message that is misleading, many courts have found that an advertisement is misleading even though no consumer survey was presented.[14]

3. *Literally Truthful Claims*: The courts have frequently found that a given claim is, in the context of the defendant's overall advertising, truthful. Such a finding can be made despite the presence of a survey purporting to show that the claim is false.[15]

---

13. *Johnson & Johnson v. GAC Int'l, Inc.*, 862 F.2d 975 (2d Cir. 1988); *Coca-Cola Co. v. Tropicana Products, Inc.*, 690 F.2d 312 (2d Cir. 1982).

14. *Porous Media Corp. v. Pall Corp.*, 110 F.3d 1329, 1337 (8th Cir. 1997); *William H. Morris Co. v. Group W Inc.*, 66 F.3d 255, 258-59 (9th Cir. 1995); *PPX Enterprises, Inc. v. Audiofidelity Enterprises, Inc.*, 818 F.2d 266, 272 (2d Cir. 1987); *Better Business Bureau of Houston v. Medical Directors, Inc.*, 681 F.2d 397, 403 (5th Cir. 1982); *see Cottrell, Ltd. v. Biotrol Int'l, Inc.*, 191 F.3d 1248, 1252 (10th Cir. 1999).

15. *L&F Prods. v. Procter & Gamble Co.*, 45 F.3d 709 (2d Cir. 1995) (court disregarded plaintiff's survey); *Glaxo Warner-Lambert OTC G.P. v. Johnson & Johnson Merck Consumer Pharmaceuticals Co.*, 935 F. Supp. 327, 331 (S.D.N.Y. 1996) ("The Court finds that the premise of the consumer survey is faulty and does not support a finding that consumers were misled. Not only is the defendant's advertisement literally true; it is actually true."). *See United Indus. Corp. v. The Clorox Co.*, 140 F.3d 1175 (8th Cir. 1998); *Avis Rent A Car Systems v. The Hertz Corp.*, 782 F.2d 381 (2d Cir. 1986) (defendant had a survey).

4. ***Non-Misleading Claims***: Numerous courts have found that an advertisement is neither literally false nor misleading despite the presence of consumer research which purports to show that the ad is misleading.[16]

In short, while consumer surveys are useful tools in false advertising litigation, there is no rule that they must be given blind deference. That Mead's market research expert was able to solicit consumer views regarding the *number* of doctors who should prefer SIMILAC in order for Abbott's claim to be true is simply not dispositive. The Seventh Circuit's refusal to defer to this particular aspect of Mead's survey in no way departs from established Lanham Act case law.

III.

THE SEVENTH CIRCUIT'S DECISION IS CONSISTENT WITH FTC ADVERTISING STANDARDS

Mead's argument that the Seventh Circuit's decision is inconsistent with FTC precedent is wrong. The FTC has long enforced a simple bedrock rule: an advertiser must have a "reasonable basis" for its advertising claims. *In re Pfizer*, 81 F.T.C. 23, 62 (1972); *Porter & Dietsch, Inc. v. Federal Trade Commission*, 605 F.2d 294, 302 (7th Cir. 1979). In the case of establishment claims, including professional

16. *L&F Products v. Procter & Gamble Co.*, 45 F.3d 709 (2d Cir. 1995); *Johnson & Johnson-Merck Consumer Pharms. Co. v. Rhone-Poulenc Rorer Pharms.*, 19 F.3d 125 (3d Cir. 1994); *Johnson & Johnson-Merck Consumer Products Co. v. Smithkline Beecham Corp.*, 960 F.2d 294 (2d Cir. 1992); *BellSouth Adver. & Publ'g Corp. v. Lambert Publ'g*, 45 F. Supp. 2d 1316, 1321-22 (S.D. Ala. 1999), *aff'd without op.*, 207 F.3d 663 (11th Cir. 2000).

endorsement claims for health care products, the question of whether the advertiser's data furnishes a "reasonable basis" for the claim is decided on the basis of expert testimony and other evidence regarding the quality of the substantiation in light of industry practice and standards.[17]

The two cases cited by Mead (Pet. 9-11) are merely examples of cases where the FTC, after reviewing the advertiser's substantiation for its professional endorsement claim, concluded that the data did not reasonably support the claim. Thus in *In re Gerber Prods. Co.*, 62 Fed. Reg. 13619 (1997), the Commission found that Gerber's "4 out of 5 pediatricians" claim was misleading because only 12% of the doctors in the survey recommended Gerber products. Similarly, in *In re Standard Brands, Inc.*, 97 F.T.C. 233 (1981), several professional endorsement claims for Fleischmann's Margarine were found to be misleading because the vast majority of doctors (67.5%) did not recommend any specific brand of margarine and, of those who did, 84.5% did not recommend Fleischmann's. In both cases the issue was the adequacy of the substantiation, not consumer opinion as to what the substantiation should be.

---

17. *E.g.*, *In re Bristol-Myers Co.*, 102 F.T.C. 21, 321 (1983), *aff'd*, 738 F.2d 554 (2d Cir. 1984); *In re American Home Prods. Corp.*, 98 F.T.C. 136 (1981), *aff'd*, 695 F.2d 681, 691-93 (3d Cir. 1982). In *In re Del Pharms., Inc.*, No. 972-3084 (F.T.C. 1998), the consent decree provided that Del's professional endorsement claim must be based upon "competent and reliable scientific evidence" consisting of:

> [T]ests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

Mead's suggestion (Pet. 23) that the facts in *Gerber* are "almost identical" to the facts of this case is demonstrably untrue. In *Gerber*, the advertiser made a specific quantitative claim about the percentage of doctors who favored its product, *viz.*: "4 out of 5"; the claim was misleading because only 12% of all doctors in the survey recommended Gerber products. In contrast, Abbott makes *no* claim regarding the percentage of doctors who prefer SIMILAC, yet in twelve different surveys a minimum of 25% and a maximum of 64% preferred SIMILAC. Moreover, in contrast to Mead's contention, the FTC did not utilize consumer research to determine whether the number of doctors who recommended Gerber products was sufficient; like the Seventh Circuit, the FTC made that determination by examining Gerber's doctor surveys in light of Gerber's claim.

In sum, the decision below is clearly consistent with the FTC's advertising substantiation requirements. Given the uniformity of the preference for SIMILAC in the twelve doctor surveys, it is inconceivable that Abbott does not have a "reasonable basis" for its "1st Choice" claim under FTC law.

CONCLUSION

The Seventh Circuit's decision is consistent with Lanham Act case law regarding false advertising claims. The decision that was inconsistent with prevailing case law was that of the District Court, which would have turned questions of claim substantiation into issues for consumer determination on a case-by-case basis that would provide no guidance to advertisers, market research companies or their lawyers. The Seventh Circuit wisely rejected that approach. Its decision should not be disturbed.

Respectfully submitted,

DAVID O. TITTLE
BINGHAM SUMMERS
WELSH & SPILMAN
2700 Market Tower
10 West Market Street
Indianapolis, IN 46204-2982
(317) 635-8900

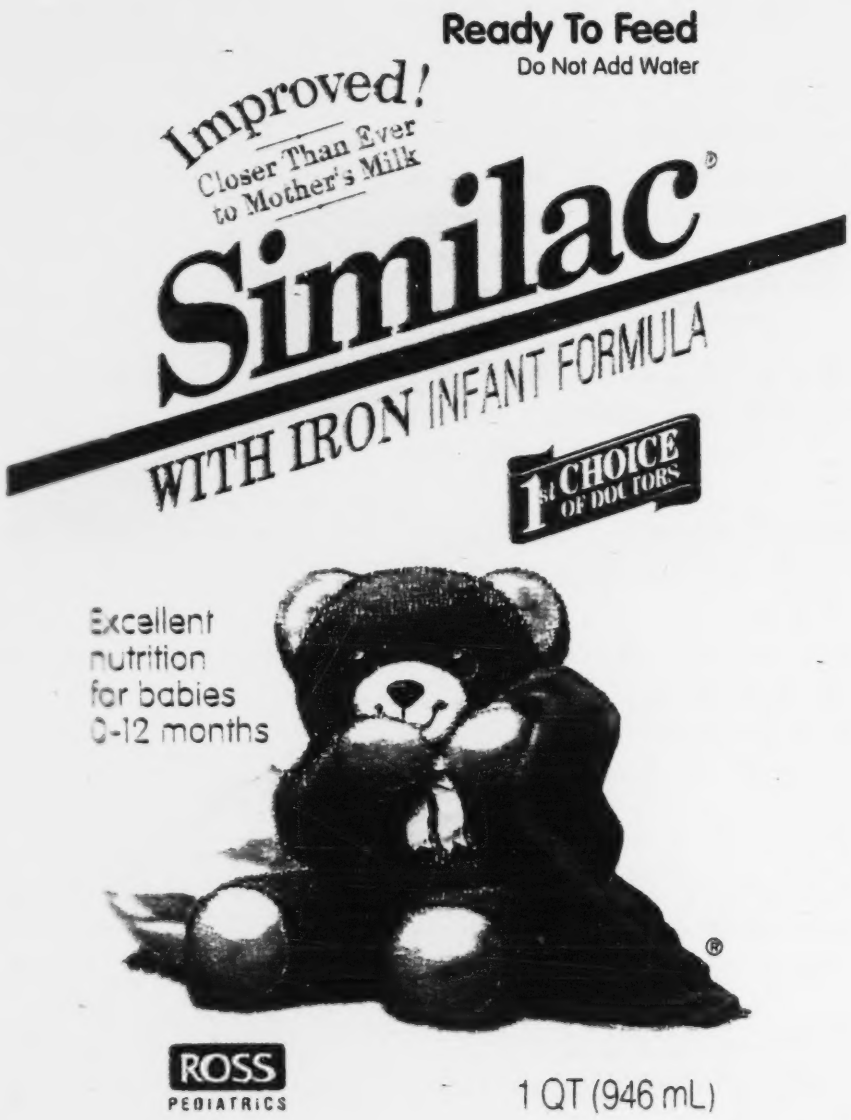
THOMAS C. MORRISON
Counsel of Record
ERIK HAAS
PATTERSON, BELKNAP,
WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036-6710
(212) 336-2000

Of Counsel:

LAURA J. SCHUMACHER
ABBOTT LABORATORIES

APPENDIX

APPENDIX A — SIMILAC PRODUCT LABEL



APPENDIX B — PROFESSIONAL ENDORSEMENT CLAIMS APPEARING IN RECENT NATIONAL ADVERTISING

1.	VICKS CHLORASEPTIC	"#1 Doctor Recommended."
2.	MONISTAT 3	"Of all the yeast infection treatments, doctors recommend MONISTAT most. MONISTAT, the number one doctor recommended brand."
3.	ZANTAC 75	"The medicine in ZANTAC 75 is the number one doctor prescribed acid reducer."
4.	TRIDENT Gum	"TRIDENT is the #1 Dentist Recommended Gum."
5.	CAPZASIN-P	"[T]he ingredient in CAPZASIN-P [is] the topical analgesic ingredient doctors recommend most for arthritis pain."
6.	CORRECTOL	"[C]ontains the ingredient recommended most by doctors for safe, dependable, overnight relief of irregularity."
7.	EXTRA-STRENGTH TYLENOL	"For headaches, doctors recommend TYLENOL the most."

Appendix B

8. CHILDREN'S TYLENOL	"The first choice of pediatricians."
9. DESITIN	"[T]he first choice of pediatricians for diaper rash."
10. LUBRIDERM	"Recommended by dermatologists more than any other leading brand."
11. URISTAT	"[T]he #1 doctor recommended brand for relieving urinary pain."
12. BABY ORAJEL	"[T]he teething brand pediatricians recommend #1."
13. TUMS	"Tums is recommended by more doctors than any other brand of calcium."
14. DOVE	"DOVE's the one that dermatologists recommend most."
15. BENADRYL	"[M]ore pediatricians recommend BENADRYL"
16. MOTRIN	"[T]he most prescribed name in the history of pain relief."

Appendix B

17. IMODIUM	"[T]he brand recommended most by doctors and pharmacists."
18. MYLANTA	"The #1 Doctor Recommended Liquid Antacid."
19. PREPARATION H	"[T]he most widely doctor-recommended OTC hemorrhoidal remedy."
20. ADVIL	"More doctors recommend ADVIL than any other brand for minor arthritis pain, backaches, menstrual cramps, and muscle aches."

Source: Lisa Davis AFF (Seventh Circuit JA 1118-1161).

APPENDIX C — RESPONSE TO Q-5 IN IVAN ROSS SURVEY

Response re Percentage of Doctors Required	Number of Respondents	Percentage of Respondents
100% all	24	8.2%
90% or more	73	24.9%
85%	8	2.7%
80%	30	10.2%
75%	40	13.7%
70%	12	4.1%
60%	21	7.2%
55%	1	.3%
51%/more than 50%	35	11.9%
Majority (without percentage stated)	1	.3%
50%/at least half	23	7.8%
Less than half	4	1.4%
No opinion/DK	17	5.8%
Non-responsive	1	.3%
Did not understand	1	.3%
Total	**293**	**100%**

***Source*: Individual Responses from Ivan Ross Consumer Survey (Trial Exh. 1).**